DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 16, 2015

HIVOX BIOTEK, INC.
Ke-Min Jen, Official Correspondent
5 F., No. 123 Shingde Road
San-chong District
New Taipei City, TW 24158

Re: K141921
Trade/Device Name: HIVOX Spopad EMS SP-910, SP-920, SP-620
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 7, 2014
Received: December 11, 2014

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141921

Device Name
HIVOX Spopad EMS SP-910, SP-920, SP-620

Indications for Use *(Describe)*
These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 5. 510(k) SUMMARY (According to 21 CFR 807.92)

| | | |
|---|---|---|
| ● | 510(K) OWNER'S NAME | HIVOX BIOTEK INC.<br>5F, No.123, Shingde Road, Sanchong Dist.,<br>New Taipei City, 24158, TAIWAN, R.O.C.<br>TEL: +886-2-85112668 FAX:+886-2-85112669 |
| ● | Name Of Contact Person | Dr. JEN, KE-MIN<br>TEL: 886-2-85112668 FAX:886-3-5209783<br>Email: ceirs.jen@msa.hinet.net |
| ● | Date Of Submission | July 5, 2014 |
| ● | Trade Name | HIVOX Spopad EMS SP-910, SP-920, SP-620 |
| ● | Common Name | Powered Muscle Stimulator |
| ● | Classification Name | Powered Muscle Stimulator<br>(21 CFR 890.5850, Product Code NGX) |
| ● | Panel | Physical Medicine |
| ● | Intended Use | These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.<br>Not intended for use in any therapy or for the treatment of any medical conditions or diseases. |
| ● | Device Design | EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relaxes stiff muscle through the skin. It is recognized as a clinically proven, effective, non-medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.<br>HIVOX Spopad EMS SP series, SP-910 / SP-920 / SP-620 are the proposed subject devices for this 510(k) submission. |

These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

SP-910 / SP-920 / SP-620 are 1-channel battery-operated user-friendly muscle stimulation systems specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910/620 comprises 2 electrodes, which connects the signals from the stimulator to the skin. SP-920 comprises 4 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.

*HIVOX BIOTEK INC.*
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Compare to Legally Marketed Predicate Devices

| Comparison items | **Predicate device 1 (PD)** | **Subject device (1)** | **Subject device (2)** | **Subject device (3)** |
|---|---|---|---|---|
| Manufacturer Submitter | SPORT-ELEC S.A. | HIVOX-BIOTEK | | |
| Device name | Body Control System | Spopad EMS, SP series | | |
| Model number | 4M | SP-910 | SP-920 | SP-620 |
| 510(k) number | K092476 | TBA | TBA | TBA |
| Product code | NGX | NGX | | |
| Classification name | Powered Muscle Stimulator | Powered Muscle Stimulator | | |
| Regulation number | 21 CFR 890.5850 | 21 CFR 890.5850 | | |
| Indications for use | Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.<br>Contraindicated use on injured or otherwise impaired muscles<br>Not intended for use in any therapy or for the treatment of any medical conditions or diseases. | Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.<br>Not intended for use in any therapy or for the treatment of any medical conditions or diseases. | | |
| Technology | Electrical Muscle Stimulation | Electrical Muscle Stimulation | | |
| Power Source | 1.5V battery *3 | 3V Battery *1 | | |
| - Method of Line Current Isolation | Battery supply | Battery Supply | | |
| - Patient Leakage Current Normal Condition (μA) | < 3 | 2.0 | | |
| Single Fault Condition(μA) | < 4 | 2.1 | | |
| Method of channel isolation | Software | 1 channel | | |

| | | | | |
|---|---|---|---|---|
| Average DC current through electrodes when device is on but no pulses are being applied | 0 µA | 0 µA | | |
| Number of output modes | 1 | 1 | | |
| Regulated current or regulated voltage? | Voltage | Voltage | | |
| Software /firmware / Microprocessor control? | Yes | Yes | | |
| Automatic overload trip? | No | No | | |
| Automatic no-load trip? | No | No | | |
| Automatic shut-off? | Yes | Yes | | |
| User overrides control? | Yes | Yes | | |
| Indicator display - On/Off Status | Yes | No | | |
| Indicator display – Low battery? | Yes | No | | |
| Indicator display – Voltage /Current | No | No | | |
| Timer Range (minutes) | N/A | 20 | | |
| Compliance with voluntary standards? | IEC 60601-1<br>IEC 60601-2-10<br>IEC 60601-1-2<br>IEC 60601-1-4 | IEC 60601-1<br>IEC 60601-2-10<br>IEC 60601-1-2 | | |
| Compliance with 21 CFR 898? | Yes | Yes | | |
| Housing material and construction | ABS | Silicone | | |
| Output waveform | Monophasic | Symmetrical biphasic | | |
| Shape | Rectangular | Rectangular | | |
| Duration of primary (depolarizing) phase | 0 | 0 | | |
| Pulse duration (µSec) | N/A | 400 | | |
| Maximum output voltage (Voltage, +/-10%) at 500 ohms | N/A | 52 | 58.4 | 60 |
| Maximum output voltage (Voltage, +/-10%) at 2k ohms | N/A | 102 | 106 | 109 |
| Maximum output voltage (Voltage, +/-10%) at 10k ohms | N/A | 150 | 146 | 140 |

| | | | | | |
|---|---|---|---|---|---|
| Maximum output current (mA +/-10%) at 500 ohms | | N/A | 104 | 117 | 120 |
| Maximum output current (mA +/-10%) at 2k ohms | | N/A | 51 | 53 | 54.5 |
| Maximum output current (mA +/-10%) at 10k ohms | | N/A | 15 | 14.6 | 14 |
| Frequency (Hz) | | N/A | 3/4/5 | 2/4/25 | 2/4/25 |
| Net charge per pulse at 500 ohms (μC) | | N/A | 0.416 | 0.468 | 0.960 |
| Maximum charge at 500 ohms (μC) | | N/A | 41.6 | 46.8 | 48 |
| Maximum current density at 500 ohms ($mA/cm^2$) | | < 2 | 1.328 | 1.057 | 1.952 |
| Maximum average power density at 500 ohms ($W/cm^2$) | | < 0.25 | 0.0691 | 0.0617 | 0.117 |
| Burst mode | A. Pulse per burst | N/A | N/A | 25 | 25 |
| | B. Burst per second | N/A | N/A | 1 | 1 |
| | C. Burst duration (sec) | N/A | N/A | 20 | 20 |
| | D. Duty cycle | N/A | N/A | 20 | 20 |

**Summary of comparison**

Basically, the predicate device and Subject Devices are all Over-The-Counter muscle stimulators. Thus, the indications for use for the devices do not differ much.

PD and Subject Devices are all battery-powered, thus electric hazards or safety do not raise much concern, since maximum current / power densities for the devices are all less than 2 (mA/cm2) / 0.25 (W/cm2), which are the FDA recommended ratings. Since the electric output data for PD and Subject Devices only exist minor differences, the minor differences of the electric outputs do not raise any safety and effectiveness aspect. PD and Subject Devices all have the same safety and effectiveness, especially they all pass medical device electric safety standard, IEC 60601-1 and standard for Nerve and Muscle Stimulator, IEC 60601-2-10 and electromagnetic compatibility standard IEC 60601-1-2.

We know that for effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts. PD should meet these requirements. Subject Devices meet these requirements too. PD and Subject Devices are all validating-software processing, thus keeping regular processing parameters and safety functions normal. The Subject Devices have the same effectiveness as the predicate device.

In conclusion, the Subject Devices do not raise any new safety and effectiveness aspect with respect to the PD. Thus the Subject Devices are **substantially equivalent** to the predicate device.